

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 17-1772V

Filed: November 1, 2022

PUBLISHED

KIMBERLY TRUETT,

Petitioner,

v.

SECRETARY OF HEALTH AND
HUMAN SERVICES,

Respondent.

Special Master Horner

Shoulder Injury Related to
Vaccine Administration
("SIRVA"); Table Injury; Cause-
in-fact; Cervical Radiculopathy;
Influenza ("flu") vaccine

*Leah Durant, Law Offices of Leah V. Durant, PLLC, Washington, DC, for petitioner.
Parisa Tabassian, U.S. Department of Justice, Washington, DC, for respondent.*

DECISION¹

On November 13, 2017, petitioner, Kimberly Truett, filed a petition under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-10-34 (2012),² alleging that she suffered "injuries, including shoulder pain and injury" resulting from adverse effects of her October 31, 2016 influenza ("flu") vaccination. (ECF No. 1.) For the reasons set forth below, I conclude that petitioner is not entitled to compensation.

I. Applicable Statutory Scheme

Under the National Vaccine Injury Compensation Program, compensation awards are made to individuals who have suffered injuries after receiving vaccines. In general, to gain an award, a petitioner must make a number of factual demonstrations, including showing that an individual received a vaccination covered by the statute;

¹ Because this decision contains a reasoned explanation for the special master's action in this case, it will be posted on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. See 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the decision will be available to anyone with access to the Internet.** In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information the disclosure of which would constitute an unwarranted invasion of privacy. If the special master, upon review, agrees that the identified material fits within this definition, it will be redacted from public access.

² Within this decision, all citations to § 300aa will be the relevant sections of the Vaccine Act at 42 U.S.C. § 300aa-10-34.

received it in the United States; suffered a serious, long-standing injury; and has received no previous award or settlement on account of the injury. Finally – and the key question in most cases under the Program – the petitioner must also establish a causal link between the vaccination and the injury. In some cases, the petitioner may simply demonstrate the occurrence of what has been called a “Table Injury.” That is, it may be shown that the vaccine recipient suffered an injury of the type enumerated in the “Vaccine Injury Table,” corresponding to the vaccination in question, within an applicable time period following the vaccination also specified in the Table. If so, the Table Injury is presumed to have been caused by the vaccination, and the petitioner is automatically entitled to compensation, unless it is affirmatively shown that the injury was caused by some factor other than the vaccination. § 300aa-13(a)(1)(A); § 300 aa-11(c)(1)(C)(i); § 300aa-14(a); § 300aa-13(a)(1)(B).

As relevant here, the Vaccine Injury Table lists a Shoulder Injury Related to Vaccine Administration or “SIRVA” as a compensable injury if it occurs within 48 hours of administration of a vaccination. § 300aa-14(a) as amended by 42 CFR § 100.3. Table Injury cases are guided by statutory “Qualifications and aids in interpretation” (“QAIs”), which provide more detailed explanation of what should be considered when determining whether a petitioner has actually suffered an injury listed on the Vaccine Injury Table. 42 CFR § 100.3(c). To be considered a “Table SIRVA,” petitioner must show that her injury fits within the following definition:

SIRVA manifests as shoulder pain and limited range of motion occurring after the administration of a vaccine intended for intramuscular administration in the upper arm. These symptoms are thought to occur as a result of unintended injection of vaccine antigen or trauma from the needle into and around the underlying bursa of the shoulder resulting in an inflammatory reaction. SIRVA is caused by an injury to the musculoskeletal structures of the shoulder (e.g. tendons, ligaments, bursae, etc.). SIRVA is not a neurological injury and abnormalities on neurological examination or nerve conduction studies (NCS) and/or electromyographic (EMG) studies would not support SIRVA as a diagnosis A vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following:

- (i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection;
- (ii) Pain occurs within the specified time-frame;
- (iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and
- (iv) No other condition or abnormality is present that would explain the patient's symptoms (e.g. NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

42 CFR §100.3(c)(10).

Alternatively, if no injury falling within the Table can be shown, the petitioner may still demonstrate entitlement to an award by showing that the vaccine recipient's injury or death was caused-in-fact by the vaccination in question. § 300aa-13(a)(1)(A); § 300aa-11(c)(1)(C)(ii). To so demonstrate, a petitioner must show that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly ex rel. Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010) (quoting *Shyface v. Sec'y of Health & Human Servs.*, 165 F.3d 1344, 1352–53 (Fed. Cir. 1999)); *Pafford v. Sec'y of Health & Human Servs.*, 451 F.3d 1352, 1355 (Fed. Cir. 2006). In particular, a petitioner must show by preponderant evidence: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of proximate temporal relationship between vaccination and injury in order to prove causation-in-fact. *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005).

For both Table and Non-Table claims, Vaccine Program petitioners must establish their claim by a "preponderance of the evidence". § 300aa-13(a). That is, a petitioner must present evidence sufficient to show "that the existence of a fact is more probable than its nonexistence" *Moberly*, 592 F.3d at 1322 n.2. Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Human Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991). However, a petitioner may not receive a Vaccine Program award based solely on her assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. § 300aa-13(a)(1). Once a petitioner has established their *prima facie* case, the burden then shifts to respondent to prove, also by preponderant evidence, that the alleged injury was caused by a factor unrelated to vaccination. *Althen*, 418 F.3d at 1278 (citations omitted); § 300aa-13(a)(1)(B).

In this case, petitioner stresses that she suffered a left-sided shoulder injury consistent with a SIRVA Table Injury. (See ECF No. 67, pp. 6-20.) Alternatively, petitioner asserts that reliable medical evidence supports a non-Table shoulder injury caused-in-fact by her vaccination. (*Id.* at 21-23.)

II. Procedural History

This case was originally assigned to the Special Processing Unit ("SPU") for expedited resolution based on the allegations of the petition. (ECF No. 5.) Petitioner filed medical records marked as Exhibits 1-5 and an affidavit marked as Exhibit 6 on November 24, 2017. (ECF No. 7.) She filed further records marked as Exhibits 7-9 and a statement of completion on February 26, 2018. (ECF Nos. 10-11.)

Settlement discussions commenced in August of 2018. (ECF No. 19.) However, on February 25, 2019, petitioner advised in a status report that the parties had very different views regarding both entitlement and damages such that petitioner did not think the case would resolve informally. (ECF No. 27.) Thereafter, petitioner filed updated medical records marked as Exhibits 10-11. (ECF No. 29.) Respondent then

filed his Rule 4 Report on April 11, 2019. (ECF No. 31.) In his Rule 4 Report, respondent concluded that the case is not appropriate for compensation. (ECF No. 31, p. 1.) Respondent contended that petitioner's injury was not consistent with a Table Injury of SIRVA, mostly notably due to her diagnosis of cervical radiculopathy, but also suggesting that timing of onset was not consistent with SIRVA. (*Id.* at 6.) To the extent petitioner could theoretically prove causation-in-fact, the record compiled at the time did not contain any expert report or other medical opinion to support vaccine causation. (*Id.* at 7.)

Petitioner filed an expert report by orthopedist Clifford Colwell, M.D., on October 28, 2019. (ECF No. 38; Exs. 12-14.) Dr. Colwell's opinion was limited to opining that petitioner qualified for a Table Injury of SIRVA, explaining why he opines that the timing is correct for a SIRVA and why a shoulder pathology is more likely than neurologic injury such as cervical radiculopathy. (Ex. 12, pp. 2-3.) After reviewing Dr. Colwell's report, respondent advised that settlement remained unlikely. (ECF No. 40.) The case was then reassigned to the undersigned's docket on December 10, 2019. (ECF No. 42.) Respondent filed a responsive expert report by orthopedist Brian Feeley, M.D., on January 16, 2020. (ECF No. 43; Exs. A-B.) Dr. Feeley opined that petitioner more likely suffered cervical radiculopathy than SIRVA and also that the timing of onset was outside of the period for a SIRVA. (Ex. A, p. 9.) Petitioner filed a report by Dr. Colwell responding to Dr. Feeley's opinion along with updated medical records on March 23, 2020. (ECF No. 44; Exs. 15-16.) Dr. Colwell maintained his opinion. (Ex. 15.)

Thereafter, I held a status conference on March 31, 2020, providing my preliminary view of the case and discussing how to proceed. (ECF No. 45.) I explained that "[b]ecause of the neurological findings referenced in Dr. Feeley's report, I think it is unlikely that this case would resolve as a Table claim. I also think, as a cause-in-fact claim, it will be a very close case, in large part, because there are limited objective findings with regard to both the proposed muscular-skeletal and neurological explanations for petitioner's symptoms." (*Id.* at 1.) I required petitioner to file transcribed physical therapy records, confirm the identity of the neurologist referenced in her prior affidavit,³ and obtain the report from a November 6, 2019, MRI referenced in the medical records. (*Id.* at 1-2.) I also ordered petitioner to file a further report by Dr. Colwell addressing causation-in-fact. (*Id.* at 2.) Petitioner filed these items on June 1, 2020. (ECF No. 48; Ex. 17-25.) Thereafter, the parties attempted to resume settlement discussions, but concluded that they remained futile. (ECF No. 49.)

Subsequently, respondent filed a second report by Dr. Feeley and an additional report by neurologist Brian Callaghan, M.D., on September 8, 2020. (ECF No. 50; Exs. C-E.) Petitioner responded on November 23, 2020, with a report from a different

³ In her affidavit, petitioner indicated that her neurologist had concluded that she suffered nerve damage caused by her flu shot. (Ex. 6, ¶ 6.) However, this was not reflected in the neurology records that had been filed to date from Dr. Zuniga-Barboni. (Ex. 5.) Accordingly, I directed petitioner to confirm whether she ever saw any other neurologist. (ECF No. 45, pp. 1-2.) In a follow up affidavit dated April 9, 2020, petitioner confirmed that she did not see any other neurologist and that Dr. Zuniga-Barboni is the neurologist referenced in her prior affidavit. (ECF No. 48-1; Ex. 17.)

orthopedist, Uma Srikumaran, M.D. (ECF No. 54; Exs. 26-36.) Later, on February 16, 2021, petitioner filed a report by neurologist Syed Ahmed, M.D. (ECF No. 57; Exs. 37-38.) Thereafter, the parties advised in a joint status report of March 19, 2021, that they wished to resolve this case based on the written record after respondent filed a final report by Dr. Callaghan, which was later filed on April 12, 2021. (ECF Nos. 59, 61; Ex. F.)

Initially a briefing schedule was set (ECF No. 60); however, I subsequently referred the case for ADR and the parties requested the briefing schedule be suspended during ADR. (ECF Nos. 62-63.) The ADR effort concluded unsuccessfully on November 5, 2021. (ECF No. 64.) On January 18, 2022, petitioner filed a motion for a ruling on the written record accompanied by updated medical records (Ex. 39), a supplemental affidavit (Ex. 40) and witness statements by Richard Hammer, Andrew Truett, August Truett, and Michele Anderson (Exs. 41-44). (ECF Nos. 66-67.) Respondent filed his response on March 21, 2022. (ECF No. 68.) Petitioner filed a reply on April 14, 2022. (ECF No. 70.)

I have determined that the parties have had a full and fair opportunity to present their cases and that it is appropriate to resolve this issue without a hearing. See Vaccine Rule 8(d); Vaccine Rule 3(b)(2); *Kreizenbeck v. Sec'y of Health & Human Servs.*, 945 F.3d 1362, 1366 (Fed. Cir. 2020) (noting that “special masters must determine that the record is comprehensive and fully developed before ruling on the record.”). Accordingly, this matter is now ripe for resolution.

III. Factual History

a. As reflected in medical records

Petitioner received the flu vaccination at issue in this case in her left deltoid on October 31, 2016, through her employer. (Ex. 1.) At the time of vaccination, she was 52 years old. (*Id.*) Prior to the vaccination, petitioner had no history of shoulder pain, though she did experience neck pain (diagnosed as cervicgia⁴) throughout much of 2015. (Ex. 2, pp. 2-3, 11-12, 14.) However, there is no indication in the medical records that petitioner’s symptoms extended to her shoulder or arm. (*Id.*) Subsequent exams confirmed normal range of motion in her spine and there is no indication her cervicgia remained symptomatic at the time of vaccination. (*Id.* at 14.)

⁴ Cervicgia is more commonly known as neck pain. *Neck pain*, Wikipedia, https://en.wikipedia.org/wiki/Neck_pain (last accessed Oct. 21, 2022). “Neck pain, although felt in the neck, can be caused by numerous other spinal problems.” *Id.* Neck pain may also arise due to muscular tightness in both the neck and upper back, pinching of the nerves emanating from the cervical vertebrae, or joint disruption. *Id.* Cervical radiculopathy is caused by compression of a cervical nerve root, and depending on the location of that compression, patients experience varying patterns of pain, weakness, and absent reflexes. (Caridi et al., *Cervical radiculopathy: a review*, 7 HSSJ 265 (2011) (Ex. F).) “Cervical radiculopathy may or may not be associated with neck pain.” (*Id.*)

A little over a month following the vaccination, petitioner e-mailed her employer's human resources department. (Ex. 7, p. 2.) The e-mail states in pertinent part:

I received the flu shot on November 1 here at work. It was the most painful shot I have ever received. I could not sleep on my left side (injection in left arm) for 2 nights. I can now only sleep on it for limited periods of time. The pain has continued to worsen. I am unable to lift with my left arm (worsened by the fact that I am left handed) and have painful limited motion. After doing some research, I discovered that I have SIRVA from incorrect injection location and a needle that is too long.⁵ I will need to see a doctor about treatment, but I don't think that I should be responsible for the cost of treatment.

(*Id.*) Petitioner first sought care for her condition approximately two months after writing that e-mail (*i.e.*, three months post-vaccination). (Ex. 2, pp. 23-25.)

On February 1, 2017, petitioner presented to her primary care physician (Dr. Dharia) with chief complaints of three weeks of head congestion and "[l]eft arm pain since flu vaccine on 11/2016." (Ex. 2, p. 23.) The history of present illness indicated "[complains of] shoulder pain. [complains of] radiation of pain. [complains of] previous injury." (*Id.*) Petitioner denied "fall, tingling/numbness, weakness." (*Id.*) Dr. Dharia further recorded "[p]ressure pain/radiating at times intricep [*sic.*] since Flu vaccine administration 11/2016, Celebrex taken which helps alleviate symptoms some." (*Id.*) Petitioner was first started on Celebrex in February of 2015 when she presented for cervicgia (Ex. 2, p. 3) and had most recently been ordered to continue it in treatment of a complaint of lumbago at her last appointment prior to vaccination in May of 2016 (*Id.* at 17).

During her February 1, 2017 encounter, petitioner's review of systems for neurology noted in relevant part that petitioner had no tingling or numbness and no limb weakness. (Ex. 2, p. 23.) However, the review of systems did not include any musculoskeletal discussion. (*Id.*) No relevant physical exam was conducted as the physical exam addressed only petitioner's ears, nose and throat and respiratory system. (*Id.* at 24.) Dr. Dharia assessed triceps tendonitis and left shoulder pain of unspecified chronicity and ordered an MRI. (*Id.* at 24-25.) Petitioner's MRI, conducted two weeks later on February 14, 2017, was suboptimal due to patient movement. (*Id.* at 33.) The

⁵ Needle length is a possible contributing factor that is discussed in some of the SIRVA literature. (Atansoff et al., *supra*, at Ex. 22, pp. 8050-51; Bodor & Montalvo, *supra*, at Ex. 21, p. 586; Martin Arias et al., *supra*, at Ex. 24, p. 4874.) However, there is no evidence of record in this case indicating what length of needle was used when petitioner's vaccination was administered. In any event, petitioner bears no burden to specifically prove this point with respect to a Table claim. *Grossmann v. Sec'y of Health & Human Servs.*, No. 18-00013V, 2022 WL 779666, at *9-10, n.12 (Fed. Cl. Spec. Mstr. Feb. 15, 2022). She would not necessarily need prove needle length based on causation-in-fact either. *E.g. Kirby v. Sec'y of Health & Human Servs.*, 16-185V, 2019 WL 6336020, at n. 20 (Fed. Cl. Spec. Mstr. Nov. 1, 2019) (finding it unnecessary to resolve competing expert assumptions regarding needle length where there was no evidence as to the length of the needle used, albeit in the context of a different injury), *review granted, decision rev'd*, 148 Fed Cl. 530 (2020), *rev'd*, 997 F.3d 1378 (Fed. Cir. 2021).

impression was (1) mild chronic supraspinatus and mild chronic subscapularis tendinosis and (2) laterally downsloping acromion. (*Id.* at 34.)

Petitioner was seen by an orthopedist (Dr. Van Sice) on February 21, 2017, for review of her MRI. (Ex. 4, pp. 1-3.) The history of present illness indicates that petitioner's shoulder pain "is located laterally. The pain/problem began on [] 11/01/2016. The pain/problem was not due to an injury, sudden in onset after having the flu shot. On a pain scale of 1 to 10, 10 being excruciating, the pain was reported as a 4. The pain is described as dull, aching." (*Id.* at 1.) The review of systems for neurology denied numbness or tingling. (*Id.*) Notations regarding physical exam were limited to noting "positive impingement signs" for the left shoulder. (*Id.* at 2.) Neurologic exam showed normal reflexes and an intact sensory exam. (*Id.*) Petitioner was assessed with myositis⁶ of the left shoulder and four weeks of physical therapy was recommended.

Petitioner then presented for a physical therapy evaluation on February 28, 2017.⁷ (Ex. 3, pp. 1-4, 16-18.) The chief complaint reflects that petitioner reported an immediate onset of severe pain following her vaccination. (*Id.* at 2.) However, the history misstates that petitioner saw an orthopedist after only two days. (*Id.*) Petitioner reported "that her symptoms are different some days but she has increased pain with lifting and has noted significant decrease in overall strength of her dominant left arm." (*Id.*) Petitioner again reported pain of four out of ten. (*Id.*) Petitioner had generalized tenderness of her left bicep and triceps but had normal range of motion. (*Id.*) For strength, petitioner was noted to have reduced strength at the elbow, wrist, and shoulder. (Ex. 3, p. 2.) Neurologic noted "Bilateral C5, C6, C7 2/3."⁸ (*Id.*) Petitioner reported functional limitations as "difficulty with any lifting or carrying activities as well as repetitive activities such as typing using her dominant left hand due to weakness, pain and fatigue." (*Id.*)

⁶ "Myositis," also called "inflammatory myopathy," is "inflammation of a voluntary muscle." *Myositis*, DORLAND'S MEDICAL DICTIONARY ONLINE, <https://www.dorlandsonline.com/dorland/definition?id=32923> (last accessed Oct. 24, 2022).

⁷ The initial evaluation record itself is dated February 20, 2017. (Ex. 3, p. 2.) However, this appears to be a mistake. As explained above, petitioner's encounter with Dr. Van Sice was on the 21st and that is also the date of the physical therapy order form. (Ex. 3, p. 1.) Petitioner's handwritten intake forms are all dated February 28, 2017 (*Id.* at 16-18) and her progress notes also indicate her first treatment date was February 28 (*Id.* at 7, 14). A transcribed copy of the daily notes later filed by petitioner as Exhibit 18 likewise indicates the date of the initial evaluation was February 28, 2017. (Ex. 18, p. 1.)

⁸ This notation is ambiguous but seems to suggest that the physical therapist believed a relevant cervical finding was present at the time of the initial evaluation. As part of the initial evaluation the physical therapist check marked that among petitioner's therapy goals would be demonstrating proper neck care. (Ex. 3, p. 3.) However, the first time petitioner is recorded as having specifically complained of neck pain to her physical therapist is the daily note of March 18, 2017. (Ex. 18, p. 1.)

Petitioner continued her physical therapy through May 2, 2017.⁹ (Ex. 3, pp. 14-15.) On March 22, 2017, petitioner was recertified to continue her physical therapy beyond the originally ordered four weeks. (*Id.* at 5-6.) At that time petitioner was reportedly making “slow but steady progress.” (*Id.* at 5.) However, she also reported “that she has less pain in the arm most of the time although increased left shoulder soreness both posterior and anteriorly and at times into the left side of her neck.” (*Id.*) Petitioner again had normal range of motion but reduced strength in the elbow, wrist, and shoulder. (*Id.*)

Petitioner returned for a follow up with her orthopedist on May 2, 2017. (Ex. 4, pp. 6-7.) Petitioner reiterated a history of sudden onset following vaccination and Dr. Van Sice further recorded that physical therapy “partially alleviates the symptoms.” (*Id.* at 6.) He recorded that “[t]he left shoulder pain occurs randomly. The left shoulder pain is described as aching and associated with arm weakness, arm pain, and difficulty sleeping. The left shoulder pain is 3 out of 10 currently. She reports occasional functional limitations and difficulty lifting objects/weight. Since the last visit her condition is better.” (*Id.*) Review of systems was positive for joint pain but negative for numbness and tingling. (*Id.*) Dr. Van Sice conducted an exam of both the cervical spine and upper extremities and recorded no abnormalities. (*Id.*) The impression was now cervical radiculopathy and a cervical spine MRI was ordered due to the fact that petitioner’s pain was not responding to conservative therapy. (*Id.* at 7.) Dr. Van Sice included an additional notation in the record indicating that “[p]atient associated symptoms with flu shot I will obtain MRI of cervical spine but also recommend follow up with neurologist.” (*Id.*)

Petitioner had a cervical spine MRI on May 5, 2017. (Ex. 4, pp. 13-14.) The impression was (1) mild canal stenosis at C5-C6, (2) moderate to severe bilateral neuroforaminal narrowing at C5-C6, (3) moderate, left greater than right, neural foraminal narrowing at C4-C5, and (4) mild bilateral neural foraminal narrowing at C3-C4. (*Id.* at 14.) Petitioner returned to Dr. Van Sice for further follow up on May 11, 2017. (Ex. 10, pp. 1-3.) Upon review of the MRI, Dr. Van Sice maintained his impression of cervical radiculopathy. (*Id.* at 2.) The plan was for follow up as needed (“PRN”). (*Id.*) It is also noted that petitioner was separately seeing a chiropractor. (*Id.* at 1.)

Petitioner was discharged from physical therapy on June 7, 2017, because she did not return to therapy for greater than 30 days. When contacted, petitioner indicated “she was feeling good and was waiting until after her neurologist appointment . . .” (Ex. 18, p. 8.) Petitioner’s physical therapy discharge indicated that she “showed inconsistent progress with overall improvement but continued complaints of left shoulder soreness at times into her neck. She reported that she was able to lift more weight at the gym and had returned to running activities.” (*Id.*)

⁹ The individual session notes included within Exhibit 3 are handwritten. For a transcribed copy see Exhibit 18 at pages 1-2.

On June 7, 2017, petitioner presented to a neurologist (Dr. Zuniga-Barboni). (Ex. 5, pp. 9-10.) Petitioner's reason for appointment was "arm pain & weakness." (*Id.* at 9.) Petitioner reported a history of left shoulder pain following a flu vaccine. (*Id.*) She explained that her shoulder MRI was "essentially normal" and that physical therapy did not help her pain (it "just moved the pain around").¹⁰ (*Id.*) Neither Advil nor Celebrex helped. (*Id.*) The pain "varies throughout the day" and "some days it does not bother her much at all." (*Id.*) Petitioner reported that she was told she had a herniated cervical disc, but she disagreed that her symptoms were related. (Ex. 5, p. 9.) She noted that she sometimes has "a shooting pain down the left arm" and that her physical therapy helped with her fingers. (*Id.*) Past medical history noted both prior back and neck pain. (*Id.*)

Review of systems recorded pain in both the left shoulder and neck, but no numbness or tingling. (Ex. 5, p. 10.) Dr. Zuniga-Barboni confirmed review of both the prior shoulder and neck MRIs. (*Id.*) On physical examination petitioner had full range of motion for both her neck and all joints. (*Id.* at 9.) Petitioner had full strength throughout, including her deltoid, but had reduced pinprick sensation in her left arm and hand. (*Id.* at 10.) An EMG showed minimal neuropathic changes in the left posterior deltoid, left triceps, and right "FDI,"¹¹ but no active denervation. (*Id.*) The assessments were (1) "Unspecified disturbances of skin sensation . . . with minimal neuropathic changes in the posterior branch of the axillary nerve to the deltoid but no denervation or weakness," (2) "Other spondylosis with radiculopathy, cervical region . . . with intermittent neck pain and spasms," and (3) "Spinal stenosis, cervical region." (*Id.* at 10.) Petitioner was recommended Voltaren Gel for her disturbance of skin sensation and continued activity for strengthening the left arm. (*Id.*) No further follow up was scheduled at that time. (*Id.*) Petitioner filed the instant action about five months later on November 13, 2017. (ECF No. 1.)

After receiving Dr. Zuniga-Barboni's neurology assessment, petitioner did not seek further treatment for nearly two years. Then, on March 22, 2019, petitioner

¹⁰ Petitioner's suggestion that her physical therapy is responsible for changing her symptoms is not necessarily borne out by the physical therapist's daily notes. (Ex. 18, pp. 1-2.) These records reflect that petitioner occasionally came to physical therapy reporting changes in her symptoms associated with her daily life, but repeatedly record that she tolerated her therapy well with no increase in symptoms. For example, on March 8, 2017, petitioner "reports pushed down on arm to get out of chair today and had shooting pain. Twisting at the gym caused radiating pain down her arm." (*Id.* at 1.) On March 18, 2017, petitioner reported "neck and posterior shoulder a little sore today." (*Id.*) On April 6, 2017, petitioner reported "arm a little sore from using it more this week." (*Id.* at 2.) On April 14, 2017, petitioner reported "feeling a little better did some upper body exercise at the gym without increased symptoms today." (*Id.*) On April 24, 2017, petitioner reported "sore last few days near acromioclavicular joint unsure why." (Ex. 18, p. 2.) On April 28, 2017, petitioner reported "she woke up with left upper trap and scapular pain, unsure why. She just doesn't feel quite right." (*Id.*) April 28, 2017 is the only date during which it is noted that petitioner's therapy increased symptoms. (*Id.*)

¹¹ This likely refers to "first dorsal interosseous." See Davis, Neil M., *Medical Abbreviations*, 16th Ed. (2020), p. 226. The dorsal interosseous are muscles of the hand. *Musculi interossei dorsalis manus*, DORLAND'S MEDICAL DICTIONARY ONLINE, <https://www.dorlandsonline.com/dorland/definition?id=90756> Petitioner would later report a prior history of an unspecified right hand surgery. (Ex. 39, p. 13.)

returned to her primary care physician (Dr. Dharia). (Ex. 11.) At that time the chief complaint indicated “Left shoulder pain (deltoid) since 2016 – neurologist said nothing else can be done- have also been to pt, that didn’t help- made it travel and radiate up my arm.” (*Id.* at 1.) In the history of present illness, however, petitioner indicated that her pain is localized to the left upper arm and denies radiation of pain. (*Id.*) No physical examination was recorded. Petitioner was assessed as having “left arm pain.” (*Id.*) She was started on prednisone and directed to follow up in May. (*Id.* at 1-2.)

On November 6, 2019, she presented to a different orthopedist (Dr. Simovitch) for “follow up left shoulder pain.”¹² (Ex. 16, pp. 1-3.) This encounter record notes petitioner to have an active history of neck pain but does not otherwise include any history of present illness or physical examination. The assessment was “shoulder joint pain” and an MRI was ordered. (*Id.* at 1-2.) A further notation indicates “Did discuss possibility of exploratory surgery possible arthroscopic subacromial decompression.” (*Id.* at 1.)

Petitioner underwent a left shoulder MRI on November 13, 2019. (Ex. 19.) The impression was (1) “Narrowing of the acromiohumeral distance to 4mm, consistent with the clinical signs of impingement. There is mild lateral downsloping of the acromion again noted as well as a small os acromiale variant along the anterior margin of the acromion.” (2) “Supraspinatus tendinopathy with bursal surface fraying distally. Additional subscapularis tendinopathy and infraspinatus insertional tendinopathy.” (*Id.* at 2.)

Petitioner returned to Dr. Simovich on January 8, 2020. (Ex. 16, pp. 4-6.) Physical exam recorded no neurologic abnormalities. (*Id.* at 6.) Musculoskeletal exam indicated no tenderness to palpation. (*Id.*) Active range of motion was recorded as 170 degrees flexion, 170 degrees of abduction, 60 degrees of external rotation and internal rotation to L1. (*Id.*) Passive range of motion was full. (*Id.*) Neer and Hawkins signs¹³ were positive for impingement and Speed’s and O’Brien’s tests were negative. (*Id.*) The diagnosis was impingement. (Ex. 16, p. 6.) Dr. Simovich recommended home exercises and NSAIDs and explained that the condition can become progressively worse over time. (*Id.*)

¹² In her supplemental affidavit, petitioner indicates that she saw Dr. Simovitch five times, in September and October of 2019, January and September of 2020, and March of 2021. (Ex. 40, p. 3.) However, the records that have been filed reflect encounter dates of November 6, 2019, and January 8, 2020, September 28, 2020, March 17, 2021, and September 29, 2021. (Exs. 11, 39.)

¹³ The Neer Impingement Test “is a test designed to reproduce symptoms of rotator cuff impingement through flexing the shoulder and pressure application. Symptoms should be reproduced if there is a problem with the supraspinatus or biceps brachii.” *Neer Impingement Test*, WIKIPEDIA, https://en.wikipedia.org/wiki/Neer_Impingement_Test (last accessed Oct. 24, 2022). A positive Hawkins-Kennedy test is indicative of an impingement of all structures that are located between the greater tubercle of the humerus and the coracohumeral ligament.” *Hawkins-Kennedy test*, WIKIPEDIA, https://en.wikipedia.org/wiki/Hawkins%E2%80%93Kennedy_test (last accessed Oct. 24, 2022). The impinged structures include the supraspinatus muscle, teres minor muscle, and the infraspinatus muscle. *Id.*

Petitioner again returned to Dr. Simovich on September 28, 2020. (Ex. 39, pp. 7-12.) Petitioner complained of a five-year history of shoulder pain she attributed to her flu vaccine. (*Id.* at 7.) The shoulder pain was aching, diffuse, and intermittent. (*Id.*) It was reportedly helped by a prior cortisone shot the prior October. (*Id.*) The history of present illness further reflects that “[t]he pain is mechanical. It is caused by position of the arm. Denies any change in the pain in the left shoulder with positioning of her cervical spine.” (*Id.*) Physical examination showed full strength and range of motion and no tenderness to palpation. (*Id.* at 8.) All special tests, including Neer and Hawkins, were negative. (*Id.* at 9.) Dr. Simovich administered a cortisone injection. (Ex. 39, p. 10.) Under general assessment and plan, Dr. Simovich recorded: “After the review of both history and physical examination of [petitioner] a diagnosis of left shoulder pain and adhesive capsulitis with impingement has been determined. The clinical and radiographic findings were discussed in detail.” (*Id.*) Under additional notes, Dr. Simovich further recorded that “[p]atient’s history is consistent with the onset of pain status post flu shot. The two are correlated. There are no signs of radicular type pain. We do not believe that the current limitations of the left shoulder are referred from the cervical spine.” (*Id.* at 11.)

Petitioner returned to Dr. Simovich again on March 17, 2021. (Ex. 39, pp. 1-5.) Petitioner reported no improvement and that her pain is “referred around the deltoid insertion area.” (*Id.* at 1.) On physical examination, petitioner had normal strength but decreased abduction and external rotation. (*Id.* at 2.) All special tests were negative, except for the Hawkins sign, which was positive. (*Id.* at 2-3.) The assessment was unchanged and Dr. Simovich further recorded that “I explained the nature of the injury. Namely that the aberrant injection results in a reaction within the shoulder that can cause changes of the bursa sac and surrounding rotator cuff tissue. This ultimately leads to pain. Also can precipitate the onset of adhesive capsulitis.” (*Id.* at 5.)

Petitioner returned to Dr. Simovich again on September 29, 2021. (Ex. 39, pp. 13-17.) Petitioner reported no improvement but explained that she felt her range of motion had mostly normalized with pain at the extremes of range. (*Id.* at 13.) Dr. Simovich seemed to suggest arthroscopic surgery would be the only remaining treatment option. (*Id.* at 16.) No further records were filed.

b. As reflected in witness statements

i. Petitioner’s affidavits

Petitioner’s first affidavit is dated October 6, 2017. (Ex. 6.) Petitioner avers that when she received her October 31, 2016 vaccination the injection itself was “extremely painful” and different from prior vaccinations. (*Id.* at 1.) She indicates her arm throbbed afterward. (*Id.*) She further states that “[i]n the days that followed, I was unable to sleep well due to the throbbing pain in my left arm. I tried taking Advil and Tylenol, but nothing helped. The remainder of the week was very difficult at work and home due to the lack of sleep and pain in my arm.” (*Id.*) This was exacerbated by the fact that she is left-handed. (*Id.*) Petitioner reports that as a single parent, and with Christmas on the

way, she could not afford to see the doctor right away. She indicates that she reached out to her employer, but to no avail. She indicates “I received no treatment and my left arm became weaker and weaker because I was unable to use it for lifting.” (*Id.*) She tried to continue strength training at the gym, but it made the pain worse. (*Id.* at 2.) After Christmas travel and once health insurance funds became available as of the new year, petitioner sought care. (*Id.*)

Petitioner reports that the physical therapy she was prescribed did not improve her pain and the pain “began to radiate to additional locations in my arm and shoulder and even extended from my upper arm into my upper left back near my shoulder blades.” (Ex. 6, p. 2.) Petitioner characterizes her physical therapy as “unsuccessful” and explains that her orthopedist subsequently “had no idea why I was still experiencing pain.” (*Id.*) She notes that he suspected cervical radiculopathy and that a follow up MRI showed a herniated disc “completely unrelated to the flu shot injury.” (*Id.*)

Petitioner indicates that she then “took it upon myself to locate a neurologist who may be able to offer some answers and pain relief.” (Ex. 6, p. 2.) According to petitioner, the neurologist she consulted “concluded that I had nerve damage from the flu shot. It most likely occurred when the needle pinched the nerve against the bone when the needle went into my bone. The doctor told me that the damage to the nerve had healed.” (*Id.*) In a second affidavit dated April 9, 2020, petitioner confirms that the above-referenced neurologist is Dr. Zuniga-Barboni, M.D. (Ex. 17.)

Petitioner filed an additional affidavit in connection with her motion for a ruling on the written record. (Ex. 40.) Petitioner reiterates the intensity of her initial pain and notes that she could not carry anything greater than two pounds following the vaccination. (*Id.* at 1.) She also expresses that she has not slept soundly since receiving the vaccination. (*Id.*) She explains how her injury has affected her gym routine as well as her golf and paddle board hobbies. (*Id.* at 2.) Finally, petitioner explains that there are large gaps in her medical records due to doctors telling her “that he/she could find nothing wrong OR that there was nothing that could be done.” Petitioner describes Dr. Ryan Simovich, who she says she “finally found” in the autumn of 2019, as the doctor that “seems to understand my injury.” (*Id.* at 3.) Petitioner has not yet determined whether she will pursue arthroscopic shoulder surgery. (*Id.*)

ii. Additional witness statements

Richard Hammer is petitioner’s partner. (Ex. 41, p. 1.) They have lived together since June of 2016. (*Id.*) Mr. Hammer describes the effect petitioner’s condition has had on her life and specifically states “unequivocally that her shoulder was completely fine until she received that flu shot.” (*Id.*) He indicates petitioner has experienced shoulder pain “continuously for nearly 5 years [that] originated from the flu shot . . .” (*Id.*) However, Mr. Hammer did not describe a specific date of onset or describe the specific circumstances by which he first became aware of petitioner’s injury.

Andrew Truett is petitioner's son. (Ex. 42, p. 1.) Mr. Truett indicates that "[f]rom the time [petitioner] received the shot, I remember her not being able to use her arm to lift anything due to the discomfort. This made it difficult for her to do many day-to-day things like grocery shopping, lifting the laundry basket, and taking out garbage to name a few." (*Id.*) He recalls her having previously been physically fit and active. (*Id.*)

Austin Truett is petitioner's son. (Ex. 43, p. 1.) He indicates that he was away at college during the period in question but recalls that on "multiple occasions my mother mention[ed] the pain from the shot in her shoulder bothering her." (*Id.*) He recalls that every time he has seen petitioner since the injury, she has needed assistance lifting objects. (*Id.*) He further recalls that petitioner had restricted range of motion because she was unable to hang Christmas tree ornaments higher than shoulder height.¹⁴ (*Id.*) He notes that prior to this injury, petitioner had been lifting weights at the gym on a regular basis since about 2004 or 2005. (*Id.*)

Michele Anderson is petitioner's sister. (Ex. 44, p. 1.) Ms. Anderson recalls that the Christmas following petitioner's October 2016 flu vaccination, "she was having trouble with gifts and her luggage. She could no longer lift anything with any weight due to the pain and discomfort in her arm." (*Id.*)

IV. Expert Reports

a. Petitioner's experts

i. Orthopedist Clifford W. Colwell, Jr., M.D.¹⁵

Dr. Colwell wrote three reports for this case. (Exs. 12, 15, 20.) In his first report, dated October 28, 2019, Dr. Colwell reviews the medical records filed through petitioner's Exhibit 11, *i.e.*, records up to and including petitioner's March 22, 2019 encounter with Dr. Dharia. (Ex. 12.) He opines that these records show that petitioner

¹⁴ No year is specified with regard to this recollection and Mr. Truett explains the injury persisted for five years. (Ex. 43.)

¹⁵ Dr. Cowell serves as the medical director of the Shiley Center for Orthopaedic Research and Education at Scripps Clinic where he acts as the Donald and Darlene Shiley Chair in Orthopaedic Research. (Ex. 12, p. 1.) He previously served as a clinical professor in the Department of Orthopaedics and Rehabilitation at the University of California, San Diego, School of Medicine, and an adjunct clinical professor at the Department of Basic Science and Clinical Research at the Scripps Research Institute. (*Id.*) Dr. Cowell served as the chief of the Orthopaedic Division at Scripps Clinic and Director of the Lower Extremity Reconstruction Fellowship Program for twenty years. (*Id.*) Dr. Cowell received his medical degree from the University of Michigan in 1962. (Ex. 13, p. 1.) He completed his orthopaedic residency at the Hospital for Special Surgery in New York City, and completed a trauma fellowship at Los Angeles County Hospital. (*Id.*) Dr. Colwell is board certified in orthopaedic surgery. (*Id.* at 3.) Between 1968-1970 Dr. Cowell served in the military as an orthopaedic surgeon at Carswell Air Force Base in Fort Worth, Texas. (*Id.* at 1.) Dr. Colwell has authored over 260 peer-reviewed papers, as well as 19 book chapters, including work related to total shoulder arthroplasty. (*Id.* at pp. 7-21.) He currently serves as the editor for Bone and Joint Disease: Index and Review journal and The Journal of Arthroplasty. (*Id.* at 6.)

had no prior history of shoulder pain and that onset of petitioner's post-vaccination shoulder pain occurred within 48 hours of vaccination. (*Id.* at 1-2.) With regard to the scope of her injury, Dr. Colwell acknowledges that petitioner reported pain radiating down her arm (*i.e.*, not limited to her shoulder), but feels this was unlikely to be neurologic because it was infrequent and her EMG did not show evidence of denervation. (*Id.* at 2.) Dr. Colwell opines that the EMG was "essentially negative." (*Id.* at 3.)

Dr. Colwell opines that it is "very unlikely" that cervical radiculopathy explains petitioner's condition. (Ex. 12, p. 3.) Dr. Colwell acknowledges that the diagnosis of cervical radiculopathy and cervical spinal stenosis were made by petitioner's neurologist (Dr. Zuniga-Barboni) based on MRI, but opines that there was no opinion offered that these diagnoses explained her shoulder symptoms. (*Id.*) This is based on the fact that Dr. Zuniga-Barboni recorded as part of the history of present illness that petitioner reported that "[s]he was also told she had a herniated disc in her neck but that they did not feel was related to her symptoms." (*Id.* (citing Ex. 5, p. 9).) Dr. Colwell posits that Dr. Zuniga-Barboni "presumably agreed with the doctors" who told petitioner this. (*Id.*) Finally, Dr. Colwell posits that petitioner would not have been advised to continue shoulder strengthening exercises if a "true neurologic problem" existed. (*Id.*)

In his second report, dated March 23, 2020, Dr. Colwell confirms that he is unmoved by Dr. Feeley's competing opinion. (Ex. 15.) Dr. Colwell stresses with regard to onset that petitioner was a consistent historian. (*Id.* at 1.) He also opines that "[m]y belief that her pain is related to her shoulder rather than the cervical spine is based on how her treating doctors managed her condition. None of her physicians treated her condition as one involving cervical spine issues." (*Id.* at 2.) He further opines that in his view, petitioner's complaints were "not generally complaining of cervical pain radiating from the neck." (*Id.*) He stresses that a cervical etiology does not explain the sudden onset and that the exercise program she was prescribed was unlikely to address cervical radiculopathy. (*Id.*)

In his third report, dated May 28, 2020, Dr. Colwell concedes that Dr. Feeley is likely correct that radiating cervical spine pain would likely be in the differential diagnosis, but contends that a direct shoulder injury should be the top diagnosis in the differential.¹⁶ (Ex. 20, pp. 1-2.) He also addresses causation-in-fact. (*Id.*) Dr. Cowell bases his causation-in-fact opinion on several pieces of literature supporting a causal relationship between vaccination and deltoid bursitis. (S. Atanasoff et al., *Shoulder injury related to vaccine administration (SIRVA)*, 28 VACCINE 8049 (2010) (Ex. 22); Mark Bodor & Enoch Montalvo, *vaccination-related shoulder dysfunction*, 25 VACCINE 585 (2007) (Ex. 21); Stratton et al., Committee to Review Adverse Effects of Vaccines, Institute of Medicine, eds., *Adverse Effects of Vaccines: Evidence and Causality*, Washington (DC): National Academies Press (2011) (Ex. 23) (hereinafter "IOM

¹⁶ However, Dr. Callaghan in particular stresses in response to Dr. Colwell's report that cervical radiculopathy was the final diagnosis of both Dr. Van Sice and Dr. Zuniga-Barboni rather than part of a differential diagnosis. (Ex. D, p. 4.)

Report”); L.H. Martin Arias et al., *Risk of bursitis and other injuries and dysfunctions of the shoulder following vaccinations*, 35 VACCINE 4870 (2017) (Ex. 24); Elisabeth Hesse et al., *Shoulder injury related to vaccine administration (SIRVA): petitioner claims to the National Vaccine Injury Compensation Program, 2010-2016*, 38 VACCINE 1076 (2020) (Ex. 25).) Accordingly, Dr. Colwell opines that “[i]t is likely that during the injection some amount of the antigenic material was injected into the subacromial bursa and joint resulting in an immune related inflammatory response.” (Ex. 20, p. 3.)

ii. Orthopedist Uma Srikumaran, M.D., MBA, MPH¹⁷

Dr. Srikumaran wrote one report dated November 10, 2020. (Ex. 26.) It is the final orthopedic expert report filed in the case. Dr. Srikumaran’s report includes observations responsive to both of the other orthopedic experts, Dr. Colwell for petitioner and Dr. Feeley for respondent, but offers no comment on Dr. Callaghan’s previously filed neurology report. (See *id.*) Dr. Ahmed’s first report and Dr. Callaghan’s second report were filed subsequent to Dr. Srikumaran’s report.

Dr. Srikumaran agrees with Dr. Colwell’s assessment that the medical records speak to an abrupt and immediate post-vaccination onset of shoulder pain. (Ex. 26, p. 7.) However, Dr. Srikumaran distinguishes his assessment from Dr. Colwell’s in that he opines that cervical radiculopathy was present. (*Id.* at 11.) Nonetheless, he also disagrees with respondent’s experts insofar as he does not believe cervical radiculopathy explains all of petitioner’s symptoms to the exclusion of any shoulder pathology. (*Id.*) Moreover, he opines that “the time course suggests she started to experience shoulder and arm pain first, and this later led to her cervical pain, neither of which she had any evidence of prior to vaccination.” (*Id.*)

Citing Bokshan et al, Dr. Srikumaran explains that painful shoulder impingement may occur in up to 24% of patients with cervical radiculopathy. “Pain reported in the neck may represent referred pain from the shoulder girdle or vice versa.” (Ex. 26, p. 9 (quoting Steven L. Bokshan, *An evidence-based approach to differentiating the cause of shoulder and cervical spine pain*, 129(9) AM. J. MED. 913 (2016) (Ex. 28).) Dr. Srikumaran stresses the Bokshan authors’ explanation that “[i]n more diagnostically complex cases, patients with cervical pain may have positive provocative shoulder test

¹⁷ Dr. Srikumaran serves as an associate professor in the Shoulder Division at the Johns Hopkins School of Medicine and serves as the Shoulder Fellowship Director and Chair of Orthopaedic Surgery for the Howard County General Hospital. (Ex. 26, p. 1.) He also serves as the Medical Director of the Johns Hopkins Musculoskeletal Service Line in Columbia, Maryland. (*Id.*) Each year Dr. Srikumaran sees approximately 2500-3000 patients for shoulder issues and performs 400-500 shoulder surgeries annually. (*Id.*) He has treated approximately ten to twelve patients with shoulder dysfunction after vaccination in the past five years. (*Id.*) Dr. Srikumaran received his medical degree from Johns Hopkins School of Medicine in 2005. (Ex. 27, p. 1.) He completed his orthopaedic residency at Johns Hopkins Hospital and completed a shoulder surgery fellowship at Massachusetts General Hospital. (*Id.*) Dr. Srikumaran is board certified in orthopaedic surgery. (*Id.* at 10.) He peer reviews journal articles for several orthopaedic journals including The Journal of Bone & Joint Surgery, Orthopedics, Clinical Orthopedics and Related Research, and The Journal of Shoulder and Elbow Surgery. (Ex. 26, pp. 1-2.) Dr. Srikumaran was selected to serve on the Shoulder and Elbow Content Committee for the American Academy of Orthopaedic Surgery. (*Id.*)

results” believed to be caused by muscular spasms or dysfunction of the numerous muscles that connect the shoulder and neck. (*Id.* at 10 (quoting Bokshal et al., *supra*, at Ex. 28, p. 916).) Based on his own clinical experience, Dr. Srikumaran suggests that “[i]t is typical for patients with shoulder pain to attempt to mitigate their pain by adjusting their shoulder girdle (shoulder blade) with the previously mentioned muscles, which may lead to spasms and alter their neck position and mechanics. This, in turn, can result in neck pain, causing a previously asymptomatic neck condition (disc degeneration / arthritis) to become symptomatic. (*Id.*) Dr. Srikumaran cites two papers for the proposition that among patients presenting with both positive shoulder and cervical tests, treatment of shoulder pain resolves neck pain in a majority of cases. (*Id.* (citing Richard Hawkins et al., *Cervical spine and shoulder pain*, 258 CLIN. ORTHO. & RELATED RESEARCH 143 (1990) (Ex. 35); Stephen Manifold & Peter McCann, *Cervical radiculitis and shoulder disorders*, 368 CLIN. ORTHO & RELATED RESEARCH 105 (1999) (Ex. 36)).)

In terms of how petitioner’s shoulder pathology could have been vaccine-caused, Dr. Srikumaran provided a fuller explanation of causation-in-fact than Dr. Cowell, but also relied on much of the same literature. (Atanasoff et al., *supra*, at Ex. 22; Martin Arias et al., *supra*, at 24; Bodor & Montalvo, *supra*, at Ex. 21; Bokshan, *supra*, at Ex. 28; Hawkins et al., *supra*, at Ex. 36; Hesse et al., *supra*, at Ex. 25; Jerrold Gorski & Lawrence Schwartz, *Shoulder impingement presenting as neck pain*, 85-A(4) J. BONE & JOINT SURG. 635 (2003) (Ex. 30); Elizabeth Hesse et al., *Risk for subdeltoid bursitis after influenza vaccination*, 173 ANN. INTERN. MED. 253 (2020) (Ex. 31); Beth Hibbs et al., *Reports of atypical shoulder pain and dysfunction following inactivated influenza vaccine*, Vaccine Adverse Event Report System (VAERS), 2010-2017, 38 Vaccine 1137 (2020) (Ex. 32); Manifold & McCann, *supra*, at Ex. 36; C. Trollmo et al., *Intra-articular immunization induces strong systemic immune response in humans*, 82 CLIN. EXP. IMMUNOL. 384 (1990) (Ex. 33); Qiuling Shi et al., *People in pain: do they seek relief?* 8(8) J. PAIN 624 (2007) (Ex. 34).)

iii. Neurologist Syed Saif Ahmed, M.D.¹⁸

Dr. Ahmed wrote one report for this case dated February 16, 2021. (Ex. 37.) Dr. Ahmed confirms his review of the previously filed expert reports by Drs. Colwell, Srikumaran, Feeley and Callaghan, but does not directly address any of their contentions. (*Id.* at 1.) Dr. Ahmed stresses that most older individuals will have some cervical changes visible on MRI and it is therefore important to distinguish between MRI changes and clinical diagnosis. (*Id.* at 2.) “An abnormal MRI does not diagnose

¹⁸ Dr. Ahmed graduated from Ross University School of Medicine in 2005, completed an internship in internal medicine at the Prince George’s Medical Center, and then began his neurology residency at Ohio State Wexner School of Medicine, where he served as chief resident in 2009. (Exs. 37, 38.) After he completed a fellowship in sleep medicine in 2010 at St. Vincent’s Hospital at the University of Massachusetts. (Ex. 37, p. 1.) Dr. Ahmed is board certified in neurology with a practice in Germantown, Maryland. (*Id.*) He serves as the managing director of the Capital Neurology and Sleep Medicine practice. (*Id.*) Dr. Ahmed sees approximately 5,000 patients each year, including 1,000 patients suffering from cervical radiculopathy. (*Id.*) Dr. Ahmed is a member of the American Academy of Neurology and the American Academy of Sleep Medicine (AASM). (*Id.*)

cervical radiculopathy” (*Id.*) Dr. Ahmed notes that “I have not seen any patients in my practice who initially presented with cervical radiculopathy with only very specific shoulder pain.” (*Id.*) Moreover, Dr. Ahmed explains that cervical radiculopathy is a clinical diagnosis that often needs a trigger, such as trauma or strain, and would not be likely to start within 24-48 hours after a vaccination. (*Id.* at 2-3.)

In petitioner’s case, Dr. Ahmed notes that at the time of onset petitioner had no complaints of radiating pain, which would be “typically seen in radiculopathy.”¹⁹ (Ex. 37, p. 2.) He also indicates petitioner had no complaints of neuropathic pain. (*Id.*) Further, Dr. Van Sice documented a normal cervical spine exam on May 11, 2017. (*Id.* (citing Ex. 10).) Dr. Ahmed characterizes petitioner’s EMG results as “minimal” with no evidence of denervation and stresses that her shoulder MRI also had relevant findings. (*Id.*) Thus, Dr. Ahmed opines that petitioner’s shoulder pain is not attributable to cervical radiculopathy. (*Id.*)

Nonetheless, Dr. Ahmed further indicates that “[a]ny preexisting radiculopathy was likely made symptomatic by the shoulder injury. I believe the vaccination was the most likely trigger for bringing about the shoulder pain as well as the left sided neck pain which was previously asymptomatic.” (Ex. 37, p. 2.)

b. Respondent’s experts

i. Orthopedist Brian Feeley, M.D.²⁰

Dr. Feeley wrote two reports dated January 10, 2020, and September 1, 2020. (Exs. A, C.) Dr. Feeley’s first report is responsive to Dr. Colwell’s initial report. In his first report, Dr. Feeley explains cervical radiculopathy as follows:

Cervical radiculopathy refers to the condition where there is compression on the cervical nerve roots as they exit the spine and begin to traverse down the neck into the upper extremities. The clinical presentation can be variable, with neck pain that is associated with radiculopathy more often unilateral than pure discogenic neck pain. The pattern of pain radiation

¹⁹ There is at least some degree of tension between this opinion by Dr. Ahmed and Dr. Srikumaran’s view that “I disagree with the respondent’s report suggestion that radiation of pain down her arm is inconsistent with SIRVA. Radiation is simply one way to characterize the pain and is common in various directions for common shoulder related diagnoses such as bursitis or capsulitis.” (Ex. 26, p. 8.) Whereas Dr. Ahmed presents radiating pain as a tell-tale symptom, Dr. Srikumaran seeks to treat it as nonspecific.

²⁰ Dr. Feeley received his medical degree from Stanford University in 2001. (Ex. B, p. 1.) He completed his orthopaedic surgery residence at University of California, Los Angeles with a focus on research in 2007, and completed the sports medicine and shoulder fellowship at the Hospital for Special Surgery in New York in 2008. (Ex. A, p. 1.) He is licensed by the state of California, the Drug Enforcement Administration, and certified by the American Board of Orthopaedic Surgery. (Ex. B, p. 1.) Dr. Feeley has served as a medical professor at the University of California, San Francisco since 2008, and is Chief of the university’s Sports Medicine and Shoulder Service. (Ex. A, pp. 1-2.) Dr. Feeley has published over 200 pieces of medical literature including medical journal articles, review articles, and medical textbook chapters. (*Id.*) He has treated over 800 patients with rotator cuff pathology in the last five years. (*Id.*)

depends on the involved nerve root, and some distributional overlap may exist. Compression of the nerve roots proximally (C4, C5) may be isolated to the shoulder girdle. These patients may not have motor or sensor problems, and may present with pain as their predominant symptom.

(Ex. A, pp. 3-4 (citing Jason Eubanks, *Cervical Radiculopathy: nonoperative management of neck pain and radicular symptoms*, 81(3) AM. FAM. PHYS. 33 (2010) (Ex. A Tab 1)).)

Cervical radiculopathy is “relatively common,” and is mainly, but not exclusively, age related. In Eubanks, et al, cited above, less than 15% of patients reported a preceding trauma and less than a quarter had objective disc protrusion visible on MRI. (Eubanks, *supra*, at 33.) Dr. Feeley indicates that “it has been suggested that inflammatory cytokines released from damaged intervertebral disks can also result in symptoms, especially in patients with MRI findings suggestive of minimal mechanical compression.” (Ex. A, p. 4.) Most patients are managed with a combination of anti-inflammatory medication and physical therapy. (*Id.*) Corticosteroid injections may be used in some cases to decrease inflammation around the affected nerve root and to reduce pain. (*Id.*) Prognosis is generally favorable, with the majority of patients not requiring surgery. (*Id.*)

In Dr. Feeley’s opinion, cervical radiculopathy is most likely the “primary cause” of petitioner’s pain. (Ex. A, p. 6.) In support of that conclusion, he cites the following factors: MRI findings of severe stenosis at C5-6 which he indicates correlate to the lateral shoulder area; an MRI of the shoulder he interprets as “essentially negative,” especially because it showed no bursitis (which he suggests constitutes a lack of confirmation of mild impingement signs noted on exam); changes to the axillary nerve on EMG, which he suggests as correlating to the area of shoulder pain; and global weakness of the upper extremity upon initial evaluation, which is more consistent with a cervical etiology than a bursitis. (*Id.*) Dr. Feeley disagrees with Dr. Colwell’s assessment of the recommendation for strengthening exercises as incompatible with a cervical radiculopathy. (*Id.* at 8.) He notes that petitioner’s neurologist offered only a non-specific suggestion, which he opines is not unreasonable, and did not prescribe physical therapy. (*Id.*) In any event, he cites to literature which he indicates supports physical therapy as a treatment for cervical radiculopathy. (*Id.* (citing Robert Boyles et al., *Effectiveness of manual physical therapy in the treatment of cervical radiculopathy: a systematic review*, 19(3) J. MANUAL & MANIPULATIVE THERAPY 135 (2011) (Ex. A, Tab 11)).)

Dr. Feeley’s second report was prompted by my request for clarification during the March 31, 2020 status conference and also includes further comments responsive to Dr. Colwell’s second report. (ECF No. 45.) In his second report, Dr. Feeley further explains that petitioner’s EMG findings, though “relatively subtle,” are consistent with the symptoms she reported of pain and weakness, including in the back of the shoulder and neck. (Ex. C, p 1 (citing Ex. 3, pp. 2, 6-18).) Dr. Feeley indicates the EMG finding is “directly related” to petitioner’s cervical radiculopathy, stressing that the C5 compression

seen on petitioner's MRI is at the location of the nerve root supplying the axillary nerve. Thus, the EMG is further evidence that "there is an anatomic source from her neck that is the primary etiology of her lateral and posterior-based shoulder pain." (*Id.*) Although he stresses that petitioner did complain of some neck pain, he further opines that it is "common" for radicular symptoms to occur in the absence of neck pain in patients carrying a primary diagnosis of cervical radiculopathy. (*Id.*) In particular, he cites Caridi, et al, for the proposition that C5 radiculopathy specifically occurs in the shoulder and radiates down the arm. (*Id.* (Caridi et al., *Cervical radiculopathy: a review*, 7 HSSJ 265 (2011) (Ex. C Tab 1)).) Finally, Dr. Feeley also endorses Dr. Callaghan's neurology opinion offered on respondent's behalf. (*Id.* at 2.)

ii. Neurologist Brian C. Callaghan, M.D., M.S.²¹

Dr. Callaghan likewise wrote two reports for this case dated August 27, 2020, and April 2, 2021. (Exs. D, F.) Dr. Callaghan's first report sets forth his overall opinion and discusses the competing opinions of Drs. Colwell and Feeley. Dr. Callaghan's second report, the final expert report filed in the case, addresses the opinions of Drs. Srikumaran and Ahmed.

Dr. Callaghan opines that the objective findings in the case favor a cervical radiculopathy. Like Dr. Feeley, he opines that the shoulder MRI was "unrevealing," especially in that it showed no evidence of bursitis. (Ex. D, pp. 3, 5.) Additionally, Dr. Callaghan disagrees with Dr. Cowell's assessment of petitioner's EMG as "essentially normal." (*Id.* at 4.) Instead, Dr. Callaghan "agree[s] with Dr. Feeley's interpretation of the EMG/NCS study. The changes seen on the EMG/NCS are related to the C5 nerve root, which supplies the axillary nerve, and not a separate problem with the axillary nerve." (*Id.* at 3.) Thus, according to Dr. Callaghan, the spinal MRI finding of moderate to severe spinal stenosis at C5/6 and left greater than right moderate neuroforaminal stenosis at C4/5 correlate to the EMG findings, both supportive of cervical radiculopathy. (*Id.* at 3-4.) Dr. Callaghan explains that the timing of petitioner's EMG, seven months after onset, can explain the lack of denervation as reinnervation can happen within that timeframe. (*Id.* at 4.)

Dr. Callaghan further stresses that these objective findings further correlate to petitioner's symptoms. Consistent with Dr. Feeley's opinion, Dr. Callaghan opines that cervical radiculopathy can present without neck pain. (Ex. D, p. 5.) Moreover, C5 and

²¹ Dr. Callaghan received his medical degree from the University of Pennsylvania Medical Center in 2004, and his Master of Science in clinical research design and statistical analysis from the University of Michigan in 2011. (Ex. E, p. 1.) He completed his residency in neurology at the University of Pennsylvania Medical Center, as well as fellowships in neuromuscular and healthcare research and policy from University of Michigan. (*Id.*) He is board certified in neurology and electrodiagnostic medicine. (*Id.*) Currently he serves as an associate professor of neurology at the University of Michigan, and as a neuromuscular specialist with a primary interest in patients with neuropathy (such as cervical radiculopathy). (Ex. D, p. 1.) He has published more than 90 articles focusing on neuropathy, including appropriate diagnostic evaluation and treatment. (*Id.*) He has treated over 200 patients with cervical radiculopathy. (*Id.*)

C6 cervical radiculopathy often present with radiation of pain into the shoulder. (*Id.*) In any event, Dr. Callaghan disagrees with Dr. Colwell's assessment that petitioner's pain was localized to her shoulder, noting instead that she "did complain of pain in the left side of her neck. She also endorsed other radicular symptoms such as left arm pain, shoulder pain with radiation in the triceps, decreased strength in her left hand and left arm, and shooting pain down her arm." (*Id.*)

Dr. Callaghan also suggests that the diagnosis of cervical radiculopathy in the medical records was final. (Ex. D, p. 4.) In particular, he notes that petitioner's neurologist, Dr. Zuniga-Burboni, reached a final diagnosis of cervical radiculopathy in consideration of petitioner's history, her spinal MRI, her EMG, and her own physical examination that revealed neuropathic symptoms at the site of the EMG abnormality. (*Id.*)

In his second report, Dr. Callaghan challenges the idea included in both Dr. Srikumaran's and Dr. Ahmed's reports that petitioner initially suffered shoulder pain only and that this later led to her cervical symptoms. (Ex. F, p. 2.) Although Dr. Callaghan agrees that cervical and shoulder conditions frequently co-occur, he considers the suggestion that shoulder pain can lead to cervical radiculopathy to be unsupported. (*Id.*) Dr. Callaghan notes that cervical radiculopathy often occurs without any clear trigger. (*Id.*) Whereas petitioner's experts suggested the greater prevalence of cervical radiculopathy may suggest overdiagnosis, Dr. Callaghan seems to suggest that, especially in light of petitioner's MRI and EMG, the prevalence of the diagnosis simply supports it as a more likely explanation. (*Id.*)

With regard to petitioner's own history, Dr. Callaghan stresses that petitioner reported pain radiating into her triceps at her first post-vaccination medical encounter. (Ex. F, p. 1.) From that point forward, petitioner reported a variety of symptoms throughout her treatment that are more consistent with cervical radiculopathy than shoulder pathology, including pain radiating to the triceps, decreased strength in the arm and hand, left-side neck pain, and shooting pain down her arm. (*Id.*) Contrary to Dr. Ahmed's assessment, Dr. Callaghan concludes that the shooting pain down petitioner's arm constitutes the type of neuropathic pain Dr. Ahmed suggested is absent. (*Id.* at 2.) According to Dr. Callaghan, the tenderness of the left biceps and triceps observed on physical exam are not consistent with SIRVA and the decreased pinprick sensation is consistent with a nerve injury such as from cervical radiculopathy. (*Id.*)

Dr. Callaghan acknowledges, as Dr. Ahmed notes, that cervical spine MRI can show pathology that is not related to symptoms. (Ex. F, p. 2.) However, he reiterates that in this case the cervical MRI and EMG findings both correlate directly with petitioner's reported symptoms. (*Id.*) Dr. Callaghan also acknowledges the shoulder MRI showed "minimal" changes but opined that "the pathology of the MRI of the cervical spine was much more severe than the pathology of the shoulder." (*Id.*)

V. Discussion

This case pits a clear and consistent perception by petitioner that her injury is vaccine-related against confounding medical evidence that leaves that perception unlikely to be accurate. As a threshold matter, respondent disputes the timing of onset in this case. However, even finding that there is little reason to doubt that petitioner's injury arose shortly after vaccination, it is still unlikely petitioner's injury was vaccine-caused. Two analyses are necessary. First, for the reasons discussed below, there is preponderant evidence that petitioner suffered a cervical radiculopathy that likely explains her clinical presentation. For that reason, petitioner's claim of a Table Injury of SIRVA fails regardless of the timing of onset. However, this merely deprives petitioner of a presumption of causation rather than entirely defeating her claim. Petitioner's second orthopedic expert, Dr. Srikumaran, has crafted a view of this case in which he opines that petitioner's admitted cervical radiculopathy itself can be explained as sequela to a vaccine-related shoulder injury. This opinion is further addressed in the context of a cause-in-fact claim under the *Althen* test. However, it too lacks preponderant support.

a. Timing of onset

Under the Vaccine Injury Table, shoulder pain must manifest within 48 hours of vaccination to qualify as a Table SIRVA. 42 CFR §100.3(a). Alternatively, in asserting petitioner's theory of cause-in-fact, Dr. Srikumaran likewise relies upon literature finding a majority of subjects experienced vaccine-caused shoulder pain within 48 hours of vaccination. (Ex. 26, p. 5.) Accordingly, the question of timing is essentially the same under either analysis.

Respondent contends that petitioner's allegation of post-vaccination onset of shoulder pain is not corroborated by her most contemporaneous medical records. (ECF No. 68, p. 16.) In sum, respondent's argument is that petitioner's first report of shoulder pain to her employer was not specific enough and her later report to her orthopedist (which is very specific) is too stale to be credited. (*Id.* at 14-16.) This issue need not be belabored as respondent's argument is simply unsupported.

Petitioner first reported her injury to her employer about one month after vaccination. She wrote: "I received the flu shot on November 1^[22] here at work. It was the most painful shot I have ever received. I could not sleep on my left side (injection in left arm) for 2 nights . . . The pain has continued to worsen." (Ex. 7, p. 2.) Subsequently, when petitioner first sought medical treatment on February 1, 2017, the history that was recorded was "[l]eft arm pain since flu vaccine 11/2016." (Ex. 2, p. 23.) When petitioner presented for orthopedic care, the history was "[t]he pain/problem began on Date: 11/01/2016. The pain/problem was not due to an injury, sudden in onset after having the flu shot." (Ex. 4, p. 1.)

²² Petitioner rather consistently mis-recalled the date of her vaccination by one day; however, because November 1 is still within 48 hours of vaccination this does not present any case determinative issue.

Considering the record as a whole, there is no basis for declining to take these records at face value in placing onset on November 1, 2016. Even at three and more months post-vaccination, the medical records were generated in the ordinary course of seeking treatment and respondent has not cited any conflicting evidence to contradict the history provided.

b. Table Injury

However, despite finding timing of onset that would be appropriate for a Table Injury, petitioner's Table Injury claim resolves based on the third and fourth QAI SIRVA criteria, which are closely related under the circumstances of this case. As explained above, in order to demonstrate a Table SIRVA, petitioner must show *inter alia* that her pain and reduced range of motion are "limited to the shoulder in which the intramuscular vaccine was administered" (criterion three) and that "[n]o other condition or abnormality is present that would explain the patient's symptoms (e.g. NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy)" (criterion four). 42 C.F.R. §100.3(c)(10).

Citing *Werning v. Sec'y of Health & Human Servs.*, No. 18-267V, 2020 WL 5051154 (Fed. Cl. Spec. Mstr. July 27, 2020), petitioner argues with respect to criterion three that "radiating pain does not preclude petitioner from bringing a Table claim." (ECF No. 67, p. 13.) Petitioner contends that her medical records consistently confirm the presence of a shoulder injury and that her expert opined that radiation of pain is simply "one way to characterize pain" and is consistent with a shoulder injury. (*Id.*) With respect to the fourth criterion, petitioner argues that "[c]learly, individuals who suffer from asymptomatic^[23] cervical radiculopathy, which includes virtually everyone over the age of 50, can still suffer from a SIRVA injury. It is not the mere presence of cervical radiculopathy that automatically invalidates a Table claim." (*Id.* at 14.) Petitioner contends that "the language of Criterion (iv) is intended to preclude a Table claim when there is a *better* or *more likely* explanation for the shoulder pain, especially if it is neurologic in nature." (*Id.* at 16 (emphasis original).)

These arguments are unpersuasive on this record, because when considering the record as a whole I *do* find that cervical radiculopathy is the better or more likely explanation for petitioner's condition. Several factors contribute to this conclusion.

i. Treating physician opinions

The process for making determinations in Vaccine Program cases regarding factual issues begins with consideration of the medical records. § 300aa-11(c)(2). The special master is required to consider "all [] relevant medical and scientific evidence

²³ Though petitioner's cervical radiculopathy was seemingly asymptomatic at the time of vaccination, Dr. Srikumaran states more broadly in his report that petitioner "has no history or reports of neck pain or symptomatic cervical degeneration/radiculopathy prior to her vaccination." (Ex. 26, p. 7.) As discussed in the factual summary above, this is not correct. Petitioner complained of neck pain multiple times during 2015 and these complaints were diagnosed as cervicgia. (Ex. 2, pp. 2-3, 11-12, 14.)

contained in the record,” including “any diagnosis, conclusion, medical judgment, or autopsy or coroner’s report which is contained in the record regarding the nature, causation, and aggravation of the petitioner’s illness, disability, injury, condition, or death.” § 300aa-13(b)(1)(A).

Here, following onset of her condition, petitioner had a four-month course of treatment beginning in February 2017. During that period, petitioner consulted her primary care physician, an orthopedist, a physical therapist, and a neurologist. She had a shoulder MRI, a spinal MRI, an EMG, and multiple physical examinations. Each of these physicians was made aware of petitioner’s reported history of an immediate post-vaccination onset. Shoulder pathology was explored; however, when considering the history, physical examinations, response to physical therapy treatment, and objective testing, both petitioner’s treating orthopedist and neurologist, Drs. Van Sice and Zuniga-Barboni respectively, came to the same final conclusion that petitioner’s diagnosis was cervical radiculopathy. (Ex. 4, pp. 6-7; Ex. 5, pp. 9-10.) These conclusions weigh heavily against petitioner’s claim.

Petitioner raises two responses to this fact, neither of which is persuasive. First, petitioner notes that she subsequently saw a second orthopedist, Dr. Simovich, who reached a different conclusion. Second, petitioner suggests primarily via Dr. Colwell’s reports that petitioner’s cervical radiculopathy diagnosis was only part of a differential diagnosis.

Dr. Simovich’s diagnostic opinion carries less weight than that of Drs. Van Sice and Zuniga-Barboni. First, Dr. Simovich first saw petitioner over three years post-vaccination and after a nearly two-year gap in treatment.²⁴ Second, Dr. Simovich’s assessment appears to be based on an incomplete, if not incorrect, history. Dr. Simovich’s history of present illness indicates only that petitioner had previously been diagnosed with impingement with no indication he was aware of Drs. Van Sice’s and Zuniga-Barboni’s more contemporaneous diagnosis of cervical radiculopathy. (Ex. 16, p. 5.) Dr. Van Sice acknowledges petitioner had a prior history of neck pain, but indicates it began May 19, 2017. (*Id.*) Dr. Simovich does not include any record notation that would suggest he reviewed petitioner’s prior medical records or her prior cervical MRI and EMG results. (See Ex. 19, p. 1.) (However, the November 2019 shoulder study was compared to the February 2017 shoulder study). To the extent his diagnosis was based on a subsequent November 2019 MRI and upon his own physical examinations, Dr. Simovich’s assessment may be a reasonable assessment of petitioner’s condition as of late 2019; however, his basis for assessing petitioner’s 2017 condition is lacking.²⁵

²⁴ In fact, petitioner first presented to Dr. Simovich on November 6, 2019, after respondent filed his Rule 4(c) report, where respondent contended that petitioner’s injury was not consistent with a Table injury of SIRVA, mostly notably due to her diagnosis of cervical radiculopathy. (ECF No. 31, p. 6. (filed 4/11/2019).)

²⁵ It should be noted that the 2019 MRI study is not fully consistent with the prior 2017 study. In the 2019 study petitioner had an acromiohumeral distance of 4mm, which was noted to be consistent with impingement. (Ex. 19, p 1.) However, petitioner’s prior 2017 study showed a greater acromiohumeral

The extra weight often assigned treating physician opinions is premised on the notion that, in addition to being qualified to offer a medical opinion, the treating physicians were eyewitnesses with personal knowledge of the unfolding of a petitioner's condition. *Nuttall v. Sec'y of Health & Human Servs.*, 122 Fed. Cl. 821, 832-33 (2015) (explaining that the Federal Circuit "found that a treating physician who was familiar with the patient both before and after the alleged vaccine injury is likely to be in a better position than an expert retained after the fact" to opine with respect to vaccine causation), *aff'd* 640 Fed. Appx. 996 (Mem.) (Fed. Cir. 2016). Here, that type of consideration favors weighing the more contemporaneous opinions of Drs. Van Sice and Zuniga-Barboni more heavily than the far more remote assessment of Dr. Simovich.

Dr. Colwell's assessment of the earlier medical records as reflecting only a differential diagnosis was based in substantial part on a questionable reading of neurologist Dr. Zuniga-Barboni's medical record. (Ex. 20, pp. 1-2 (citing Ex. 5, p. 9).) Specifically, he opined that Dr. Zuniga-Barboni "presumably" accepted the assessment of petitioner's other doctors that petitioner's cervical condition did not explain her shoulder symptoms. (*Id.*) However, this interpretation was based solely on the fact that petitioner had reported this as part of the history of present illness. Nothing in Dr. Zuniga-Barboni's record implies the acceptance Dr. Colwell posits. Moreover, to the extent petitioner did report such a history, it is not reflected in her prior medical records. By the time petitioner saw Dr. Zuniga-Barboni, petitioner's orthopedist, Dr. Van Sice, had clearly changed his diagnosis to cervical radiculopathy and recommended petitioner consult a neurologist. (Ex. 4, pp. 6-7.)

Nor is Dr. Colwell's assessment of the records as reflecting mere differential diagnosis necessarily consistent with petitioner's own account. In her affidavit, petitioner confirms that her orthopedist's conclusion was that petitioner's condition was due to a herniated disc unrelated to her vaccination. (Ex. 6, p. 2.) She recalls that she thereafter "took it upon herself" to seek out a neurology opinion and her records confirm that petitioner suspended her physical therapy attendance pending her neurology consultation. (Ex. 6, p. 2; Ex. 18, p. 8.) When petitioner presented to Dr. Zuniga-Barboni she specifically confirmed that her prior shoulder MRI had been "essentially normal." (Ex. 5, p. 9.) Discussing her neurology consultation in her affidavit, petitioner suggests that "[a]fter several different tests on my left arm, [the neurologist] concluded that I had nerve damage from the flu shot." (Ex. 6, p. 2.) This description is not supported by the resulting medical record; however, it demonstrates that petitioner herself understood her neurologist to be assessing her entire post-vaccination presentation as neurologic.

distance of 6mm and impingement was not a part of the MRI interpretation. (Ex. 4, pp. 4-5.) In the 2019 report petitioner's tendinopathy is no longer characterized as "mild" and is accompanied by infraspinatus tendinopathy in addition to the previously observed supraspinatus and subscapularis tendinopathy. (Ex. 19, p. 2.) Additionally, as of 2019 the supraspinatus tendinopathy is accompanied by distal bursal surface fraying that was not noted on the prior study. (*Id.*)

For all of these reasons, when considering the medical records as a whole, there is preponderant evidence that petitioner's treating physicians concluded her post-vaccination presentation was due to cervical radiculopathy unrelated to her vaccination.

ii. Objective testing

In addition to treating physician opinions, special masters must also consider the medical records with respect to "the results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions." § 300aa-13(b)(1)(A).

When petitioner first presented for care, a shoulder pathology was suspected and petitioner underwent a shoulder MRI on February 14, 2017. (Ex. 4, pp. 4-5.) This MRI did show insertional tendinosis of the supraspinatus and subscapularis, but these findings were noted to be "mild and chronic." (*Id.*) In that regard, respondent's orthopedic expert, Dr. Feeley, stressed that tendinopathy can be observed on MRI in asymptomatic patients (Ex. A, p. 5) and petitioner's MRI lacked any finding of either bursitis, which would be a hallmark of SIRVA,²⁶ or impingement (*Id.* at 6, 9). According to Dr. Feeley, petitioner's MRI was "essentially negative" as a follow up to the signs of impingement noted in petitioner's initial orthopedic encounter with Dr. Van Sice. (*Id.*)

Dr. Van Sice did not offer any specific comment on the significance of the MRI finding (Ex. 4, generally); however, when petitioner later presented to Dr. Zuniga-Barboni, she reported, consistent with Dr. Feeley's opinion, that her MRI had been interpreted as "essentially normal." (Ex. 5, p. 9.) Petitioner's orthopedic experts provide little more. Dr. Colwell never affirmatively relied upon the MRI findings to support his opinion. (Exs. 12, 15, 20.) Dr. Srikumaran did rely on this MRI; however, his discussion was limited to simply disputing that it was entirely "negative." (Ex. 26, p. 11.) Considering all of this, petitioner's shoulder MRI offers some evidence of mild chronic shoulder pathology, but is not strong evidence that petitioner's clinical presentation is best explained as a shoulder injury.

In contrast, petitioner's May 5, 2017 cervical MRI showed stenosis of the cervical spine including findings that were interpreted as "moderate to severe." (Ex. 4, pp. 13-14.) Respondent's neurology and orthopedic experts are united in finding this result significant. (Ex. A, p. 6; Ex. D, pp. 3, 5.) Moreover, respondent's experts are persuasive in explaining that the location of this moderate to severe stenosis is anatomically matched to petitioner's symptom presentation. (Ex. A, p. 6; Ex. D, pp. 3, 5.) Petitioner presents an expert neurology opinion that cautions against treating MRI studies as diagnostic of cervical radiculopathy. (Ex. 37, p. 2.) In that regard, Dr. Ahmed disputes that petitioner had correlating symptomology. (*Id.*) However, Dr. Ahmed's assessment is undercut by petitioner's other expert, Dr. Srikumaran, who acknowledges that petitioner was experiencing a symptomatic cervical radiculopathy that was confirmed by her MRI. (Ex. 26, pp. 11-12.) Dr. Ahmed himself equivocates in order to conform his opinion to Dr. Srikumaran's, noting that he alternatively opines that any radiculopathy was made symptomatic by the shoulder injury. (Ex. 37, p. 2.)

²⁶ I stress, however, that petitioner is not required to demonstrate bursitis to prove a Table SIRVA.

Additionally, the record also includes an EMG finding which, while not strong evidence in itself, also tends to suggest that petitioner's cervical MRI finding is more likely to be significant. Specifically, although no denervation was present, petitioner's EMG showed minimal neuropathic changes in the left posterior deltoid and left triceps. (Ex. 5, p. 9.) Both Dr. Feeley and Dr. Callaghan opine that this EMG finding, though mild, constitutes evidence of neuropathic changes affecting the axillary nerve, which directly correlates to the cervical stenosis finding at the C5-C6 nerve root observed on petitioner's MRI. They explain that the affected axillary nerve branches from this nerve root. (Ex. A, p. 6; Ex. D, pp. 3, 5.) Dr. Ahmed acknowledges on petitioner's behalf that the EMG findings showed neuropathic changes consistent with radiculopathy but stressed that they were only mild and showed no denervation. (Ex. 37, p. 2.) Dr. Callaghan reasonably explains, however, that the timing of petitioner's EMG leaves reinnervation a likely explanation. (Ex. D, p. 4.) Thus, while the EMG standing alone may not be persuasive, it does contribute to the weight of evidence favoring cervical radiculopathy.

Based on all of the above, the objective testing performed in this case, though including evidence of both cervical and shoulder degeneration, weighs more heavily in favor of cervical radiculopathy as the explanation for petitioner's acute presentation.

iii. Expert opinions

Of course, petitioner is also permitted to prove her case through expert medical opinion. § 300aa-13(a)(1).

Here too, however, respondent's experts are persuasive in noting that a number of specific complaints raised by petitioner in the course of her treatment are more consistent with a cervical radiculopathy, including radiation of pain, "shooting" pain, neck pain, decreased pinprick sensation, and global weakness of the arm and hand. (Ex. A, p. 6; Ex. D, pp. 3-4.) By and large, petitioner's experts do not dispute the presence of these symptoms or their relationship to cervical radiculopathy but rely on the fact that they are either mild or do not preclude additional shoulder pathology. For example, Dr. Srikumaran disputes that radiating pain precludes shoulder pathology (Ex. 26, p. 8), but does acknowledge that in general it is characteristic of cervical pathology (Ex. 26, p. 9). Dr. Colwell acknowledged that petitioner had "neck issues" (Ex. 12, p. 2) but contended that she "was not generally complaining of cervical pain radiating from the neck" (Ex. 15, p. 2). Ultimately, however, he conceded that "Dr. Feeley is not incorrect that pain radiating from the cervical spine would likely be listed among the differential diagnoses in [petitioner's] case. It is a possibility that would need to be considered." (Ex. 20, p. 1.)

Dr. Srikumaran further explains that "[i]t is not unusual to have chronic degenerative conditions of both the shoulder and the neck, as by definition, both are age-related. In fact, many patients present with historical details, physical exam findings, diagnostic tests, and imaging results that can support both diagnoses." (Ex.

26, p. 8.) According to Dr. Srikumaran, “[t]his presents a diagnostic dilemma for clinicians . . . It is not always possible to differentiate between the two conditions and the anatomic region reported by the patient may mislead the clinician.” (*Id.*) With regard to petitioner’s own case, he opines that her medical providers had both shoulder and cervical diagnoses on the differential list, “[l]ooking at the complete picture there is substantial evidence consistent with shoulder pathology . . . However, I also think she has some evidence of cervical radiculopathy.” (*Id.* at 11.) Yet, “[i]n contrast to the prior experts that seem to be arguing for the primacy of one condition over the other, I believe there is adequate evidence to support both.” (*Id.*)

A primary reason Dr. Srikumaran suggests petitioner’s presentation is not solely explained by cervical radiculopathy is the presence of positive impingement signs during physical examinations in 2017 and 2020. (Ex. 26, p. 11.) When viewing the record as a whole, however, this is not strong evidence. First, Dr. Srikumaran himself quotes literature stating that “[i]n more diagnostically complex cases, patients with cervical pain may have positive provocative shoulder test results.” (Ex. 26, p. 10 (quoting Bokshan et al., *supra*, at Ex. 28, p. 916).) Dr. Srikumaran explains that this is likely due to muscle spasms in the muscles connecting the shoulder and neck. (*Id.* at 9-10.) To be sure, Dr. Srikumaran cites this phenomenon as evidence supporting his opinion that symptoms can be referred from the shoulder to the neck (*Id.*) However, he also acknowledged that the same is true “vice versa,” *i.e.* symptoms can be referred from the neck to the shoulder. (*Id.*) In that regard, petitioner’s treating neurologist, Dr. Zuniga-Barboni, specifically indicated that her assessment of cervical radiculopathy was inclusive of muscle spasms. (Ex. 5, p. 10.)

Second, these impingement signs were not well documented and were inconsistently detected. The first time petitioner saw an orthopedist, Dr. Van Sice noted the presence of “positive impingement signs” on physical exam, but did not specify what maneuvers he tested, making it difficult to assess the strength of this finding. (Ex. 4, p. 2.) Nor did he specifically include impingement in his resulting diagnosis (assessing only myositis). (*Id.*) When petitioner returned for follow up, Dr. Van Sice included no indication of impingement on physical exam of petitioner’s upper extremity conducted both May 2 and May 11 and changed his diagnosis to cervical radiculopathy. (*Id.* at 6-7; Ex. 10.) As Dr. Srikumaran observes, impingement was not noted again until three years later when petitioner saw Dr. Simovich on January 8, 2020, and his physical exam revealed positive Neer and Hawkins signs. (Ex. 16, p. 6.) However, this finding is far more remote and by the time Dr. Simovich recorded these findings subsequent MRI showed impingement that had not been present in 2017. (See n. 25, *supra*.) Dr. Simovich assessed impingement syndrome; however, as had happened with Dr. Van Sice, when petitioner returned for follow up on September 28, 2020, impingement was not noted. Dr. Simovich recorded full range of motion and specifically noted that all special tests, including Neer and Hawkins tests, were negative. (Ex. 39, pp. 8-9.) (Later exams by Dr. Simovich again found positive Hawkins sign. (See *generally* Ex. 39.))

Additionally, petitioner's experts opine that cervical radiculopathy is not a good explanation for petitioner's condition in light of her abrupt onset of symptoms. (Ex. 15, p. 2; Ex. 37, pp. 2-3.) In that regard, some literature filed in this case does suggest that a sudden onset of acute neck pain should be concerning for an alternative diagnosis. (Eubanks, *supra*, at Ex. A, Tab 1, p. 36). Moreover, cervical radiculopathy caused by chronic disc herniation generally causes insidious onset whereas sudden onset of severe symptoms is more typical of acute herniation. (Caridi et al., *supra*, at Ex. C, Tab 1, p. 266.) However, an epidemiologic survey of 561 cervical radiculopathy patients showed that a bare majority (281 patients) had an acute rather than insidious onset of symptoms. (Kurupath Radhakrishnan et al., *Epidemiology of cervical radiculopathy: A population-based study from Rochester, Minnesota, 1976 through 1990*, 117 Brain 325, 328 (1994) (Ex. A Tab 2.) Documented duration of symptoms at the time of initial evaluation was as little as one day. (*Id.*) Among the study subjects, only about 100 had a history of physical trauma preceding onset, meaning that such trauma did not explain a majority of the acute cases. (*Id.*) Thus, while the abrupt onset in this case may be a factor that could tend to favor another explanation, it would not be accurate to conclude that sudden onset is incompatible with cervical radiculopathy. In that regard, it is notable that both Dr. Van Sice and Dr. Zuniga-Barboni confirmed they were aware of petitioner's report of a sudden post-vaccination onset before diagnosing cervical radiculopathy. (Ex. 5, p. 10; Ex. 4, pp. 6-7, 13-14.)

There is no question that some confounding considerations exist for many of the reasons discussed throughout petitioner's experts' reports. However, considering the record as a whole, including the treating physicians' opinions, the objective testing, and the expert opinions, the evidence preponderates in favor of cervical radiculopathy as the more likely explanation of petitioner's condition, including her reported shoulder pain.

c. Causation-in-fact

Causation-in-fact is determined by the three-part *Althen* test. Under the first *Althen* prong, petitioner must present a general medical theory explaining that the vaccine in question "can" cause the type of injury in question. *Pafford*, 451 F.3d at 1355-56. Under the second and third prongs, petitioner must present evidence that the vaccine "did" cause petitioner's own injury. *Id.* The third prong asks whether the timing of injury in this specific case aligns with what would be expected under the general theory presented under *Althen* prong one. *Id.* at 1358. The second *Althen* prong examines the petitioner's own medical history to see if a logical sequence of cause and effect exists to support vaccine causation. *Althen*, 418 F.3d at 1278.

Shoulder injuries following vaccination are a well-known phenomenon and, as discussed above, respondent's challenge to the alleged temporal relationship in this case is lacking. However, this case does involve a medical history suggestive of a cervical condition rather than a shoulder injury. For these reasons, *Althen* prongs one and three need not be separately addressed.²⁷ This case turns on *Althen* prong two.

²⁷ Of note, I am assuming *arguendo* that petitioner has satisfied *Althen* prong one without reaching that question. In this case, respondent has specifically challenged petitioner's showing with respect to *Althen*

In *Capizzano v. Secretary of Health & Human Services*, the Federal Circuit explained that in some contexts satisfaction of *Althen* prongs one and three suggests that *Althen* prong two should not be overanalyzed. 440 F.3d 1317, 1326 (Fed. Cir. 2006) (explaining that “[a] logical sequence of cause and effect” means what it sounds like – the claimant’s theory of cause and effect must be logical . . . if a close temporal proximity, combined with the finding that the hepatitis B vaccine can cause RA, demonstrates that it is logical to conclude that the vaccine was the cause of the RA (the effect), then medical opinions to this effect are quite probative [.]”) However, the Circuit also cautioned that the second *Althen* prong “is not without meaning.” The Court explained that

There may well be a circumstance where it is found that a vaccine *can* cause the injury at issue and where the injury was temporally proximate to the vaccination, but it is illogical to conclude that the injury was actually caused by the vaccine. A claimant could satisfy the first and third prongs without satisfying the second prong when medical records and medical opinions do not suggest that the vaccine caused the injury, or where the probability of coincidence or another cause prevents the claimant from proving that the vaccine caused the injury by preponderant evidence.

Capizzano, 440 F.3d at 1327 (emphasis original). Thus, it is well established that in terms of demonstrating specific causation, temporal association alone is not enough to satisfy petitioner’s burden of proof. See, e.g., *Veryzer v. Sec’y of Health & Human Servs.*, 100 Fed. Cl. 344, 356 (2011) (explaining that “a temporal relationship alone will not demonstrate the requisite causal link and that petitioner must posit a medical theory causally connecting the vaccine and injury”); *A.Y. by J.Y. v. Sec’y of Health & Human Servs.*, 152 Fed. Cl. 588, 595 (2021)); *Forrest v. Sec’y of Health & Human Servs.*, No. 10-032V, 2017 WL 4053241, at *18 (Fed. Cl. Spec. Mstr. Aug. 10, 2017); *Cozart v. Sec’y of Health & Human Servs.*, No. 00-590V, 2015 WL 6746616, at *18 (Fed. Cl. Spec. Mstr. Oct. 15, 2015), *aff’d*, 126 Fed. Cl. 488 (2016); *Crosby v. Sec’y of Health & Human Servs.*, No. 08-799V, 2012 WL 13036266, at *37 (Fed. Cl. Spec. Mstr. June 20, 2012).

prong one and any suggestion that vaccines cause any shoulder injury other than bursitis. (ECF No. 68, pp. 24-26.) Respondent stresses that petitioner did not have bursitis and that petitioner has not specified her injury beyond invoking the “SIRVA” concept. (*Id.* at 24.) Some special masters have been willing to credit the existence of a Table Injury of SIRVA as some evidence supporting *Althen* prong one. *Nicholson v. Sec’y of Health & Human Servs.*, No. 17-1416V, *slip op.* (Fed. Cl. Spec. Mstr. Sept. 22, 2022). However, the fact of the Table Injury alone is not enough to satisfy petitioner’s burden of demonstrating a medical theory. *Grant v. Sec’y of Health & Human Servs.*, 956 F.2d 1144, 1147-48 (Fed. Cir. 1992). Moreover, given that I have concluded that petitioner has not suffered a Table Injury of SIRVA, merely accepting the Table Injury of SIRVA on its own terms as the theory of causation would then strongly suggest that petitioner’s cause-in-fact claim should necessarily fail under *Althen* prong two based on precisely the same facts that defeated the Table claim. To hold otherwise would simply extend the causal presumption provided by the Vaccine Injury Table beyond what has been provided for in the Qualifications and Aids to Interpretation. *Kelly v. Sec’y of Health & Human Servs.*, No. 17-1918V, 2022 WL 1144997, at *21 (Fed. Cl. Mar. 24, 2022).

Here, for the reasons explained above, there is preponderant evidence that petitioner's condition is best explained as cervical radiculopathy. Moreover, contrary to what Dr. Colwell asserted, the treating physician opinions preponderate in favor of cervical radiculopathy unrelated to petitioner's vaccination as the cause of her condition. Thus, this case presents the type of circumstance discussed in *Capizzano* wherein it may be "illogical" to conclude the vaccine caused petitioner's injury despite apparent temporality and the fact that, in general, vaccines can cause shoulder injuries. That is, unless Dr. Srikumaran is persuasive in suggesting that the cervical radiculopathy itself is sequela to a shoulder injury.

In that regard, Dr. Srikumaran opines that petitioner's "cervical radiculopathy and degeneration confirmed by MRI and EMG studies is a degenerative disorder, not caused by her vaccination, but very likely symptomatically exacerbated by the vaccination." (Ex. 26, pp. 11-12.) In this case, he opines that "cervical radiculopathy does not explain the shoulder symptoms . . . The cervical radiculopathy could explain the patient's neck pain and radiation of pain beyond the shoulder. These symptoms are not directly from the vaccination. I believe the vaccination triggered and exacerbated a pre-existing cervical degenerative condition."²⁸ (*Id.*) More specifically, Dr. Srikumaran suggests that it is typical for patients with shoulder pain "to attempt to mitigate their pain by adjusting their shoulder girdle (shoulder blade) . . . which may lead to spasms and alter their neck position and mechanics. This, in turn, can result in neck pain, causing a previously asymptomatic neck condition (disc degeneration/arthritis) to become symptomatic." (*Id.* at 10.) There are two primary reasons why this opinion is unpersuasive on this record.

First, as discussed above with respect to the Table Injury analysis, the evidence favoring a shoulder etiology, while not entirely absent, is not strong. In contrast to her later 2019 shoulder MRI, petitioner's 2017 MRI was not interpreted as showing signs of impingement and it showed only findings considered "mild and chronic." Moreover, it lacked the bursitis that would be a potential hallmark of the type of active inflammation associated with a SIRVA-type injury.²⁹ And, although petitioner did demonstrate signs of impingement upon some physical examinations, this was not consistently detected. As Dr. Feeley explained, it appears that Dr. Van Sice treated the 2017 MRI and petitioner's response to physical therapy as indications that failed to confirm the impingement signs noted during his initial exam. For all the same reasons discussed

²⁸ Petitioner's neurology expert, Dr. Ahmed, suggests a cervical radiculopathy was less likely to be present, but nonetheless also opined that "I believe the vaccination was the most likely trigger for bringing about the shoulder pain as well as the left sided neck pain which was previously asymptomatic." (Ex. 37, p. 2.) He added "[a] vaccination cannot cause cervical radiculopathy but here it may have made it symptomatic for the first time." (*Id.* at 3.)

²⁹ I do not reach the question of whether bursitis must necessarily be present in all instances in order to prove a logical sequence of cause and effect supporting vaccine causation of a shoulder injury. However, both Dr. Colwell and Dr. Srikumaran specifically cite literature supporting bursitis as a likely mechanism by which a vaccine may initially cause shoulder symptoms. Accordingly, if it had been present it would have strong evidence favoring causation-in-fact. Conversely, even if not treated as dispositive, the fact that it is absent here does contribute to the overall conclusion that vaccine causation is less likely when considering the record as a whole.

above with respect to the Table Injury analysis, the evidence more strongly favors a cervical etiology for petitioner's condition.

Second, Dr. Srikumaran's opinion is fundamentally based on the premise that petitioner first suffered a distinct shoulder injury and only later suffered her cervical injury. However, this is not preponderantly established by the medical record evidence. Dr. Srikumaran's effort to identify separate onset of shoulder and cervical injuries is hampered by the fact that petitioner described her symptoms inconsistently and also repeatedly explained that they were intermittent. (Ex. 4, p. 1 (describing the pain as "dull and aching"); Ex. 4, p. 6 (same); Ex. 10, p. 1 (describing pain as "aching and sharp"); Ex. 18, p. 1 (describing "shooting pain" after getting up from a chair); Ex. 5, p. 9 (pain "varies throughout the day" and "some days it does not bother her much at all"); Ex. 3, p. 2 ("symptoms are different some days"); Ex. 18, p. 8 (petitioner was "feeling good" but showed "inconsistent progress with overall improvement but continued complaints of left shoulder soreness"); Ex. 5, p. 10 (describing the pain as intermittent); Ex. 39, pp. 7-12 (same).) Furthermore, experts for both parties agree that the presence of neck pain is not in itself the answer. (Ex. A, pp. 3-4; Ex. C, p. 1; Ex. 12, p. 2; Ex. 20, p. 1.) And, finally, Dr. Feeley stresses that among the symptoms notable for being consistent with cervical radiculopathy, pain radiating to the triceps was present from the very first time petitioner sought medical treatment. (Ex. 2, p. 23.) In fact, Dr. Srikumaran stands alone among four other experts and three specialist treaters in preferring to invoke *both* shoulder and cervical pathology to explain petitioner's symptoms.

In prior cases I have reached the opposite conclusion based on a different fact patterns. *Colbert v. Sec'y of Health & Human Servs.*, No. 18-166V, 2022 WL 2232210 (Fed. Cl. Spec. Mstr. May 27, 2022); *Layne v. Sec'y of Health & Human Servs.*, 18-57V, 2022 WL 3225437 (Fed. Cl. Spec. Mstr. July 12, 2022). In those cases, there was sufficient evidence of cervical radiculopathy to defeat a Table claim under the specific language of the QAI. When turning to causation in fact, however, the petitioner did meet the three-part *Althen* test. Unlike this case, those petitioners satisfied *Althen* prong two both because they had evidence of bursitis to confirm a SIRVA-type mechanism of shoulder injury and, despite some evidence of a cervical condition, treating physician opinion favored the presence of a shoulder injury.

VI. Conclusion

Petitioner has my sympathy for what she has endured. Moreover, given the seemingly coincident timing, petitioner's personal conclusion that her pain was caused by her vaccination is very understandable. However, when she sought appropriate medical care and reported this history to her physicians, they ultimately concluded that she was suffering cervical radiculopathy rather than any shoulder condition. In the course of litigating this claim, petitioner has not been persuasive in calling that conclusion into question. Considering the record as a whole under the standards applicable in this program, petitioner has not preponderantly established either that her October 31, 2016 flu vaccination resulted in a Table SIRVA or alternatively caused-in-

fact a shoulder injury also resulting in additional cervical radiculopathy. Accordingly, petitioner is not entitled to compensation. Therefore, this case is dismissed.³⁰

IT IS SO ORDERED.

s/Daniel T. Horner

Daniel T. Horner
Special Master

³⁰ In the absence of a timely-filed motion for review of this Decision, the Clerk of the Court shall enter judgment accordingly.